IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07-204-SLR
	)	
APOTEX INC. and APOTEX CORP.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

DEFENDANTS APOTEX INC.'S AND APOTEX CORP.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants, Apotex Inc. and Apotex Corp., for their Answer, Defenses, and Counterclaims, to the complaint of MedPointe Healthcare Inc. ("Plaintiff" or "MedPointe"), state and allege as follows:

PARTIES

1. Plaintiff MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

ANSWER: Apotex Inc. and Apotex Corp. state that they are without knowledge or information sufficient to form a belief as to the truth of the averments in paragraph 1 of the Complaint, and therefore deny same.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

ANSWER: Admitted.

3. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Admitted.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted.

5. Upon information and belief, Apotex Corp. is the United States agent for Apotex Inc. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

ANSWER: Apotex Inc. and Apotex Corp. admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

6. Upon information and belief, Apotex Corp. is the United States marketing and sales agent for Apotex Inc. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Apotex Inc. manufactures and supplies the approved generic drug products to Apotex Corp., which then markets and sells those products throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States, including in this judicial district, following FDA approval; otherwise denied.

7. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. will sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States, including in this judicial district, following any FDA approval.

ANSWER: Denied, except to admit that Apotex Inc. intends to sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States following any FDA approval, unless there is Court intervention.

8. Upon information and belief, Apotex Corp. is the United States subsidiary and alter ego of Apotex Inc. Upon information and belief, for all purposes relevant to this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

ANSWER: Denied.

NATURE OF THE ACTION

9. This is a civil action for the infringement of United States Patent No. 5,164,194 ("the '194 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

ANSWER: Apotex Inc. and Apotex Corp. admit that MedPointe purports to bring an action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, for the alleged infringement of United States Patent No. 5,164,194; otherwise denied.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

11. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. is a Delaware corporation.

ANSWER: Admitted that this Court has personal jurisdiction over Apotex Corp. for this action.

12. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in Delaware through its United States subsidiary and alter ego, Apotex Corp., which is a Delaware corporation; (2) its systematic and continuous contacts with Delaware, including its contacts with its United States subsidiary and alter ego and that entity's substantial and ongoing sale of numerous generic drugs in Delaware; (3) its performance of acts, either directly or through an agent, that have caused tortious injury in Delaware in connection with a persistent course of conduct with its United States subsidiary and alter ego; (4) its consent to personal jurisdiction in this Court in connection with another action for infringement of the '194 patent, Civil Action No. 06-164-SLR.

ANSWER: Denied, except to admit that this Court has personal jurisdiction over Apotex Inc. for this action.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

ANSWER: Admitted.

THE PATENT

14. On November 17, 1992, the '194 patent, titled "Azelastine Containing Medicaments," was duly and legally issued to Asta Pharma AG as assignee. Since August 16, 2002, MedPointe has been, and continues to be, the sole owner of the '194 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '194 patent is attached hereto as Exhibit A.

ANSWER: Apotex Inc. and Apotex Corp. admit that the '194 patent, entitled "Azelastine Containing Medicaments," was issued by the United States Patent and Trademark Office on November 17, 1992, that Asta Pharma AG is listed as the assignee, and that a document purporting to be a copy of the '194 patent is attached to the Complaint. Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments in the second sentence of paragraph 14, and therefore deny same. Defendants deny all other allegations in paragraph 14.

ACTS GIVING RISE TO THIS ACTION

15. Upon information and belief, on or about December 13, 2006, Apotex submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) on or about December 13, 2006.

16. ANDA 78-621 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic ophthalmic solution product containing 0.05% azelastine hydrochloride in an aqueous solution for use in treating, *inter alia*, seasonal allergic rhinitis ("the Generic Product"). ANDA 78-621 specifically seeks FDA approval to market the Generic Product prior to the expiration of the '194 patent.

ANSWER: Denied, except to admit that ANDA 78-621 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and sale of a proposed drug

product as defined in ANDA 78-621 and that ANDA 78-621 specifically seeks FDA approval to market the proposed drug product prior to the expiration of the '194 patent.

17. ANDA 78-621 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '194 patent are either invalid, unenforceable and/or not infringed by the manufacture, use or sale of the Generic Product. MedPointe received written notification of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation on March 14, 2007.

ANSWER: The first sentence of paragraph 17 of the Complaint is admitted. With regard to the second sentence in paragraph 17, Apotex Inc. and Apotex Corp. admit that Apotex Inc. sent written notification of ANDA 78-621 to MedPointe on or about March 12, 2007.

18. Upon information and belief, consistent with its practice with respect to other generic products, Apotex Inc. has designated Apotex Corp. as its agent in the United States for purposes of filing ANDA 78-621 and for marketing and selling the Generic Product in the United States upon any approval of ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Corp. markets and sells generic drug products manufactured by Apotex Inc. throughout the United States following FDA approval. Apotex Inc. and Apotex Corp. further admit that in ANDA 78-621 filed by Apotex Inc., Apotex Inc. designated Apotex Corp. as its agent in the United States for all matters related to ANDA 78-621; otherwise denied.

19. Apotex's submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Denied.

20. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '194 patent.

ANSWER: Denied.

21. Apotex Inc. is jointly and severally liable for the infringement of the '194 patent. This is so because, upon information and belief, Apotex Inc. submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and will, *inter alia*, manufacture, offer to sell and sell the Generic Product upon receipt of any FDA approval of ANDA 78-621.

ANSWER: Denied, except to admit that Apotex Inc. submitted ANDA 78-621 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

22. Apotex Inc.'s submission of ANDA 78-621 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271 (a), (b) and/or (c).

ANSWER: Denied.

23. Apotex Corp. is jointly and severally liable for the infringement of the '194 patent, regardless of which Apotex entity actually filed ANDA 78-621 and regardless of whether it is treated as the alter ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA and will, *inter alia*, offer to sell and sell the Generic Product within the United States and this judicial district upon receipt of any FDA approval of ANDA 78-621.

ANSWER: Denied.

24. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 78-621 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '194 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '194 patent, it would further infringe the '194 patent under 35 U.S.C. § 271 (a), (b) and/or (c).

ANSWER: Denied.

25. Apotex had actual and constructive notice of the '194 patent prior to filing ANDA 78-621.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. was aware of the '194 patent at the time it filed ANDA 78-621; otherwise denied.

26. MedPointe will be irreparably harmed by Apotex's infringing activities unless those activities are enjoined by this Court. MedPointe does not have an adequate remedy at law. Both the balance of the hardships as between MedPointe and Apotex and the public interest further support this Court enjoining Apotex's infringing activities.

ANSWER: Denied.

DEFENSES

FIRST DEFENSE: INVALIDITY

27. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

SECOND DEFENSE: ANTICIPATION

28. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, for example, United States Patent Nos. 3,813,384 and 4,704,387.

THIRD DEFENSE: OBVIOUSNESS

30. The '194 patent is invalid under 35 U.S.C. § 103 over prior art including, for example, United States Patent Nos. 3,813,384; 4,704,387; 3,878,217; 4,254,129; 4,313,931; 4,430,343; Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp. 541-543; Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950) Vol. 124, pp. 283-286; Kirkegaard, J., et al., *Allergy* (1982) Vol 37, pp. 203-208; Kirkegaard, J., et al., *British Journal of Diseases of the Chest* (1983) Vol. 77, pp. 113-12; Pipkorn, U., et al., *Allergy*

(1985) Vol. 40, pp. 491-496; Vanden Bussche, G., *Drugs of the Future* (1986) Vol. 11, pp. 841-843; Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515; Diamantis, W., et al., *Pharmacologist* (1981) Vol. 23, p. 149; Diamantis, W., et al., *Pharmacologist* (1982) Vol. 24, p. 200; and Kubo, N., et al., *Jpn. J. Pharmacol.* (1987) Vol. 43, pp. 277-82. The '194 patent is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

FOURTH DEFENSE: UNENFORCEABILITY

32. The '194 patent is unenforceable because it was procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to, affirmative misrepresentations regarding the advantages and benefits of azelastine administered to prophylactically treat allergies.

33. On August 12, 1985, Jurgen Engel and Gerhard Scheffler filed an application in the PTO claiming compounds that were derivatives of azelastine and like azelastine were antiallergic and antiasthma prophylactically active. The applicants argued the compounds were better than azelastine because they could be applied as an aerosol with no, or considerably less, bitter taste. On February 16, 1987, a declaration was filed in support of patentability of the derivative compounds wherein the declarant asserted the derivatives of azelastine were superior to azelastine because "[azelastine] cannot be applied in the form of an aerosol" and that "use as an aerosol is especially

important for antiallergic and asthma prophylactic compounds." The declarant also argued the compounds of Examples 2 and 4 of the application "have almost 3 times as strong an antiallergic and asthma prophylactic action as [azelastine]." The declarant was an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 4,704,387 ("the '387 prior art patent").

34. On November 13, 1987, less than nine months from the date the declaration was filed in support of the Engel and Scheffler application, Helmut Hettche filed an application in the Federal Republic of Germany claiming azelastine containing medicaments. The application claimed azelastine medicaments administered as aerosols to prophylactically treat allergy. The application further claimed that azelastine containing medicaments administered as aerosols resulted in no bitter taste side effect. On July 12, 1990, Helmut Hettche filed an application in the United States Patent Office claiming foreign priority to the application filed in the Federal Republic of Germany on November 13, 1987.

35. On February 12, 1990, a declaration was filed in support of the '194 patent application and to overcome an obviousness rejection based in part on the '387 prior art patent. The declarant argued azelastine was twice as effective as the compound of Example 1 of the '387 prior art patent. The applicants prosecuting the patent argued these results were surprising and unexpected and supported a finding that the '194 medicaments were not obvious in view of the '387 patent. The applicants failed to inform the examiner that the '387 patent claimed five different compounds and that Example 4 was structurally closer to azelastine and should have been compared to

azelastine. The examiner, nonetheless, rejected the declaration anyway because there was an incomplete recitation of the study protocol used to obtain the results.

36. In response to the examiner's criticism of the declaration, the applicants filed a second declaration purporting to further describe the experimental method of the first experiment. However, that declaration did not describe the experiment conducted in the first declaration. Instead, it described a hypothetical experiment that involved application of azelastine directly to the nasal mucosa of research animals, an *in vivo* test. This test would have been more probative of the patentability of the application. However, the test that was actually conducted and described in the first declaration was an *in vitro* test that involved studying the effects of the drug on cells suspended in a buffered solution. The same declarant drafted both the first and second declarations and knew the second declaration did not describe the experiments actually conducted and could not be used to support patentability. The declarant was also an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 5,164,194, the patent in dispute.

37. Helmut Hettche and Jurgen Engel participated in a scheme to materially misrepresent to the PTO the advantages and disadvantages of azelastine and derivative azelastine compounds in an effort to obtain a patent monopoly on azelastine medicines and derivative medicines of azelastine. Jurgen Engel made knowingly false statements to the PTO in pursuing an application for azelastine derivatives. But for these statements, Jurgen Engel would not have been granted the '387 patent. Helmut Hettche later made knowingly false statements to the PTO in pursuing his application for azelastine

containing medicines. But for these statements, Helmute Hettche would not have been granted the '194 patent application leading to the '387 patent application.

38. Jurgen Engel was an employee at Asta-Werke while the applications leading to the '194 patent were filed and prosecuted. Helmut Hettche was also an employee of Asta-Werke and was a subordinate employee to Jurgen Engel at the time those applications were being filed. Helmut Hettche knew of the application leading to the '387 patent claiming derivative compounds to azelastine. Helmut Hettche participated in the development and testing of those compounds and was aware of the statements made in the application and prosecution. Jurgen Engel was also aware Hettche was developing the medicaments claimed in the '194 patent, including an aerosol of azelastine at the time he filed the application resulting in the '387 patent. In fact, both applications were prosecuted by the same U.S. law firm.

39. Helmut Hettche was aware that at least the compounds of Examples 2 and 4 of the '387 patent were almost 3 times more effective as antiallergy compounds than azelastine. Nonetheless, when prosecuting the application that resulted in the '194 patent, Hettche represented to the PTO that azelastine was twice as effective as the compound of Example 1 of the '387 patent, and that this result demonstrated azelastine was surprisingly and unexpectedly superior to the compounds disclosed in the '387 patent. Although Helmut Hettche knew the compounds of Examples 2 and 4 of the '387 patent were nearly three times as effective as azelastine, Hettche intentionally failed to disclose this fact to the PTO. The applicant knew that if he demonstrated the superior properties of the '387 compounds he would not be able to overcome a prima facie finding of obviousness by the examiner.

40. Helmut Hettche was also aware that Jurgen Engel had previously disclosed the superiority of the '387 patent compounds to the PTO. In an effort to further argue azelastine was superior to the compounds disclosed in the '387 patent and to throw the Examiner off track, the applicant misrepresented study protocols and results described in the first declaration filed in support of the application. These misrepresentations were designed to make the method of application of azelastine claimed in the '194 patent application appear superior to application of the compounds disclosed in the '387 patent administered in the same manner. In fact, Hettche never presented results of these types of comparison studies.

41. Helmut Hettche also misrepresented the state of the prior art in seeking to overcome the examiner's rejection of the Hettche application as anticipated by United States Patent No. 3,813,384 ("the '384 prior art patent"). In the paragraph bridging columns 6 and 7 of that patent, the '384 patent discloses administering azelastine "in the usual embodiments such as tablets, dragees, capsules, suppositories, drops, ointments, creams as well as injection solutions." The applicants of the '194 patent argued that this reference as interpreted by a person skilled in the art does not disclose that drops are administered to the patient. However, the applicants knew that Jurgen Engel had already argued to the PTO that the ability to administer antiallergic compounds as aerosols were important for the treatment of conditions described in the '194 patent application. It is well known in the art that aerosols are a form of administering drops. In fact, the '194 patent application admits drops are routinely administered to patients to treat allergies wherein at column 2, lines 12 through 17 the applicant states the preferred methods of administering azelastine are in the forms of "drops, ointments, [and] creams ..." These

were the exact modes of administering azelastine as disclosed in the '384 patent. Nonetheless, the applicants for the '194 patent continued to attempt to confuse and confound the examiner by arguing that one skilled in the art would not have understood the drops of azelastine disclosed in the '384 patent to be administered directly to the patient.

FIFTH DEFENSE: MISUSE

42. The '194 patent is invalid and was obtained improperly and by inequitable conduct. Knowing that the '194 patent is invalid MedPointe commenced this infringement action against Apotex. MedPointe's efforts to enforce the '194 patent, by suing for infringement and by maintaining the patent's listing in the Approved Drug Products With Therapeutic Equivalence Evaluation (also known as the "Orange Book"), constitute patent misuse.

SIXTH DEFENSE: NON-INFRINGEMENT

43. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '194 patent. ANDA 78-621 does not infringe any valid claim of the '194 patent. The proposed drug product for which approval is sought under ANDA 78-621 does not directly or indirectly infringe any valid claim of the '194 patent.

COUNTERCLAIMS

Counterclaimants Apotex Inc. and Apotex Corp. for their counterclaims against counter-defendant MedPointe Healthcare Inc. ("MedPointe") allege as follows:

PARTIES AND JURISDICTIONS

1. Apotex, Inc. is a Canadian corporation having a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. MedPointe Healthcare Inc. ("MedPointe") is a Delaware corporation having a place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

4. MedPointe purports to be the sole owner of United States Patent No. 5,164,194 ("the '194 patent"), entitled "Azelastine Containing Medicaments."

5. Apotex Inc. has submitted an Abbreviated New Drug Application ("ANDA") 78-621 for a proposed drug product containing azelastine hydrochloride for ocular administration.

6. Pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. certified to MedPointe that the '194 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the proposed drug for which ANDA 78-621 is submitted.

7. MedPointe has commenced this civil action against Apotex Inc. and Apotex Corp. alleging patent infringement.

8. This case arises under the Constitution, laws, or treaties of the United States, viz., 35 U.S.C. §§ 1-376, which is an Act of Congress relating to patents, and 21 U.S.C. § 355, which provides subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271(e)(5).

9. Venue and personal jurisdiction are proper in this district because MedPointe, *inter alia*, is subject to personal jurisdiction in this judicial district and has submitted itself to the jurisdiction of this Court.

10. A real, actual, and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and MedPointe on the other hand regarding the invalidity of the '194 patent and Apotex's non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 (2005).

COUNT I—DECLARATION OF INVALIDITY

11. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 10 as though set forth fully herein.

12. The '194 patent is invalid and/or unenforceable on grounds specified in United States Code, Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT II—DECLARATION OF ANTICIPATION

13. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 12 as though set forth fully herein.

14. The '194 patent issued November 17, 1992 from patent application number 07/551,644 filed July 12, 1990, which purported to be a continuation of patent application number 07/268,772, filed November 9, 1988, and subsequently abandoned, which purported to claim priority from German patent application number 3738681, filed November 13, 1987.

15. United States Patent No. 3,813,384 ("the '384 prior art patent") is prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

16. United States Patent No. 4,704,387 ("the '387 prior art patent") is prior art with regard to the '194 patent under one or more of the provisions of 35 U.S.C. § 102.

17. The '194 patent is invalid under 35 U.S.C. § 102 over prior art including, for example, the '384 and '387 patents.

COUNT III—DECLARATION OF OBVIOUSNESS

18. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 17 as though set forth fully herein.

19. The scope and content of the prior art includes, but is not limited to, United States Patent Nos. 3,813,384; 4,704,387; 3,878,217; 4,254,129; 4,313,931; 4,430,343; Pecoud, A., et al., *International Archives of Allergy and Applied Immunology* (1987), Vol. 82, pp. 541-543; Feinberg, S. M., *Transactions American Academy of Ophthalmology and Otolaryngology* (1950), Vol. 124, pp. 284-286; Kirkegaard, J., et al., *Allergy* (1982), Vol. 37, pp. 203-208; Kirkegaard, J., et al., *British Journal of Diseases of the Chest* (1983), Vol. 77, pp. 113-122; Pipkorn, U., et al., *Allergy* (1985), Vol. 40, pp. 491-496; Vanden Bussche, G., *Drugs of the Future* (1986), Vol. 11, pp. 841-843; Bende, M., et al., *Allergy* (1987), Vol. 42, pp. 512-515; Diamantis, W., et al., *Pharmacologist* (1981), Vol. 23, p. 149; Diamantis, W., et al., *Pharmacologist* (1982), Vol. 24, p. 200; and Kubo, N., et al., *Jpn. J. Pharmacol.* (1987), Vol. 43, pp. 277-282. The '194 is obvious in view of these references either individually, in combination with the knowledge of the person having ordinary skill in the art, or in combination with each other.

20. The differences between the subject matter claimed in the '194 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

COUNT IV—DECLARATION OF UNENFORCEABILITY

21. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 20 as though set forth fully herein.

22. The '194 patent is unenforceable because it was procured through inequitable conduct. In violation of their duty of candor to the United States Patent & Trademark Office ("PTO"), applicants for the '194 patent misled the PTO about the properties of the alleged invention claimed therein. More particularly, circumstances constituting the applicants' inequitable conduct include, but are not limited to, affirmative misrepresentations regarding the advantages and benefits of azelastine administered to prophylactically treat allergies.

23. On August 12, 1985, Jurgen Engel and Gerhard Scheffler filed an application in the PTO claiming compounds that were derivatives of azelastine and like azelastine were antiallergic and antiasthma prophylactically active. The applicants argued the compounds were better than azelastine because they could be applied as an aerosol with no, or considerably less, bitter taste. On February 16, 1987, a declaration was filed in support of patentability of the derivative compounds wherein the declarant asserted the derivatives of azelastine were superior to azelastine because "[azelastine] cannot be applied in the form of an aerosol" and that "use as an aerosol is especially

important for antiallergic and asthma prophylactic compounds." The declarant also argued the compounds of Examples 2 and 4 of the application "have almost 3 times as strong an antiallergic and asthma prophylactic action as [azelastine]." The declarant was an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as the '387 prior art patent.

24. On November 13, 1987, less than nine months from the date the declaration was filed in support of the Engel and Scheffler application, Helmut Hettche filed an application in the Federal Republic of Germany claiming azelastine containing medicaments. The application claimed azelastine medicaments administered as aerosols to prophylactically treat allergy. The application further claimed that azelastine containing medicaments administered as aerosols resulted in no bitter taste side effect. On July 12, 1990, Helmut Hettche filed an application in the United States Patent Office claiming foreign priority to the application filed in the Federal Republic of Germany on November 13, 1987.

25. On February 12, 1990, a declaration was filed in support of the '194 patent application and to overcome an obviousness rejection based in part on the '387 prior art patent. The declarant argued azelastine was twice as effective as the compound of Example 1 of the '387 prior art patent. The applicants prosecuting the patent argued these results were surprising and unexpected and supported a finding that the '194 medicaments were not obvious in view of the '387 patent. The applicants failed to inform the examiner that the '387 patent claimed five different compounds and that Example 4 was structurally closer to azelastine and should have been compared to

azelastine. The examiner, nonetheless, rejected the declaration anyway because there was an incomplete recitation of the study protocol used to obtain the results.

26. In response to the examiner's criticism of the declaration, the applicants filed a second declaration purporting to further describe the experimental method of the first experiment. However, that declaration did not describe the experiment conducted in the first declaration. Instead, it described a hypothetical experiment that involved application of azelastine directly to the nasal mucosa of research animals, an *in vivo* test. This test would have been more probative of the patentability of the application. However, the test that was actually conducted and described in the first declaration was an *in vitro* test that involved studying the effects of the drug on cells suspended in a buffered solution. The same declarant drafted both the first and second declarations and knew the second declaration did not describe the experiments actually conducted and could not be used to support patentability. The declarant was also an employee of Asta-Werke, but failed to disclose this fact to the PTO. The application later issued as U.S. Patent No. 5,164,194, the patent in dispute.

27. Helmut Hettche and Jurgen Engel participated in a scheme to materially misrepresent to the PTO the advantages and disadvantages of azelastine and derivative azelastine compounds in an effort to obtain a patent monopoly on azelastine medicines and derivative medicines of azelastine. Jurgen Engel made knowingly false statements to the PTO in pursuing an application for azelastine derivatives. But for these statements, Jurgen Engel would not have been granted the '387 patent. Helmut Hettche later made knowingly false statements to the PTO in pursuing his application for azelastine

containing medicines. But for these statements, Helmute Hettche would not have been granted the '194 patent application leading to the '387 patent application.

28. Jurgen Engel was an employee at Asta-Werke while the applications leading to the '194 patent were filed and prosecuted. Helmut Hettche was also an employee of Asta-Werke and was a subordinate employee to Jurgen Engel at the time those applications were being filed. Helmut Hettche knew of the application leading to the '387 patent claiming derivative compounds to azelastine. Helmut Hettche participated in the development and testing of those compounds and was aware of the statements made in the application and prosecution. Jurgen Engel was also aware Hettche was developing the medicaments claimed in the '194 patent, including an aerosol of azelastine at the time he filed the application resulting in the '387 patent. In fact, both applications were prosecuted by the same U.S. law firm.

29. Helmut Hettche was aware that at least the compounds of Examples 2 and 4 of the '387 patent were almost 3 times more effective as antiallergy compounds than azelastine. Nonetheless, when prosecuting the application that resulted in the '194 patent, Hettche represented to the PTO that azelastine was twice as effective as the compound of Example 1 of the '387 patent, and that this result demonstrated azelastine was surprisingly and unexpectedly superior to the compounds disclosed in the '387 patent. Although Helmut Hettche knew the compounds of Examples 2 and 4 of the '387 patent were nearly three times as effective as azelastine, Hettche intentionally failed to disclose this fact to the PTO. The applicant knew that if he demonstrated the superior properties of the '387 compounds that he would not be able to overcome a prima facie finding of obviousness by the examiner.

30. Helmut Hettche was also aware that Jurgen Engel had previously disclosed the superiority of the '387 patent compounds to the PTO. In an effort to further argue azelastine was superior to the compounds disclosed in the '387 patent and to throw the Examiner off track, the applicant misrepresented study protocols and results described in the first declaration filed in support of the application. These misrepresentations were designed to make the method of application of azelastine claimed in the '194 patent application appear superior to application of the compounds disclosed in the '387 patent administered in the same manner. In fact, Hettche never presented results of these types of comparison studies.

31. Helmut Hettche also misrepresented the state of the prior art in seeking to overcome the examiner's rejection of the Hettche application as anticipated by the '384 prior art patent. In the paragraph bridging columns 6 and 7 of that patent, the '384 prior art patent discloses administering azelastine "in the usual embodiments such as tablets, dragees, capsules, suppositories, drops, ointments, creams as well as injection solutions." The applicants of the '194 patent argued that this reference as interpreted by a person skilled in the art does not disclose that drops are administered to the patient. However, the applicants knew that Jurgen Engel had already argued to the PTO that the ability to administer antiallergic compounds as aerosols were important for the treatment of conditions described in the '194 patent application. It is well known in the art that aerosols are a form of administering drops. In fact, the '194 patent application admits drops are routinely administered to patients to treat allergies wherein at column 2, lines 12 through 17 the applicant states the preferred methods of administering azelastine are in the forms of "drops, ointments, [and] creams …" These were the exact modes of

administering azelastine as disclosed in the '384 patent. Nonetheless, the applicants for the '194 patent continued to attempt to confuse and confound the examiner by arguing that one skilled in the art would not have understood the drops of azelastine disclosed in the '384 patent to be administered directly to the patient.

32. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support that the foregoing misrepresentations and failure to disclose material prior art as set forth above were done with intent to mislead the PTO.

33. The facts and circumstances set forth in this Count IV constitute inequitable conduct on the part of the applicants, making the '194 patent unenforceable.

34. A reasonable opportunity for further investigation or discovery is likely to provide evidentiary support for other and further circumstances constituting inequitable conduct by the applicants.

COUNT V—NON-INFRINGEMENT

35. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 34 as though set forth fully herein.

36. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '194 patent. ANDA 78-621 does not infringe, either directly or indirectly, any valid claim of the '194 patent. The proposed drug product for which approval is sought under ANDA 78-621 does not directly or indirectly infringe any valid claim of the '194 patent.

DEMAND FOR JUDGEMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. pray for judgment:

a. Finding that the '194 patent is invalid and unenforceable;

b. Finding that the '194 patent is not infringed in any manner by either Apotex Inc. or Apotex Corp.;

c. Finding that this is an exceptional case under 35 U.S.C. § 285;

d. Awarding to Apotex Inc. and Apotex Corp. their costs, expenses, and reasonable attorney's fees and other relief the Court deems just.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. demand trial by jury for all issues triable by jury. This demand is contingent upon MedPointe seeking monetary damages as set forth in paragraph D of its prayer for relief in its complaint.

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Dated: May 30, 2007
798352 / 30136-001

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on May 30, 2007, the attached document was hand delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

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